REMARKS

The present amendment is responsive to the Office Action mailed March 29, 2007. Applicant submits concurrently herewith: (1) a certified copy of the priority application United Kingdom Application No. 0219512.1; and (2) a Supplemental Information Disclosure Statement.

Claims 1-10 were pending in the application. In the Office Action, claims 1-10 have been rejected. In the instant Amendment, claim 7 has been canceled, without prejudice, claims 1-6 and 8-10 have been amended, and new claims 11-15 have been added. Upon entry of the instant Amendment, claims 1-6 and 8-15 will be pending.

Claim 1 has been amended to recite an inhalation composition "consisting of" the active ingredient and the pharmaceutically acceptable particulate carrier. Support for the amendment is found throughout the specification, which clearly shows that Applicant contemplates that an aspect of the present invention includes an inhalation composition having the active ingredient and the carrier without any additional ingredient. For example, paragraph [0044] at page 9 of the specification describes a method of making the claimed composition by blending the active ingredient and the carrier. Claim 1 has also been amended to recite that the active ingredient has a "mean" particle size of less than 10 microns in diameter and that the carrier has a "mean" particle size of less than 250 microns in diameter (emphasis added). Support for the amendment is found in the specification at, *e.g.*, page 5, paragraph [0024], and page 7, paragraph [0031].

Claims 1-4 have been amended to remove the parentheses.

Claims 2-6 and 8-10 have been amended such that the word "Claim" is no longer capitalized.

Claim 9 has also been amended to spell out the acronym MDPI. Support for the amendment is found in the specification at page 8, paragraph [0037].

New claims 11-15 have been added. Support for claims 11-13 is found in the specification at, *e.g.*, page 6, lines 3-5, and page 9, paragraph [0044]. Support for claims 14-15 is found in the specification at, *e.g.*, page 10, paragraph [0046] and page 11, Table 2.

No new matter has been added by these amendments. Entry of the foregoing amendments and consideration of the following remarks are respectfully requested.

PRIORITY DOCUMENT

Applicant submits concurrently herewith a certified copy of the priority document GB 0219512.1.

THE OBJECTION TO THE SPECIFICATION

Claims 2-10 have been objected to for reciting a capitalized word "Claim." Applicant has amended the claims to replace the capitalized word with a non-capitalized word. The objection is therefore obviated and should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102

Claims 1-2 and 5-10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Haeberlin (WO 01/39745, hereinafter "*Haeberlin*"). The Examiner contends that the upper bound of the concentration of formoterol in *Haeberlin*'s dry powders is 1/400, *i.e.*, 0.25%, which overlaps (or touches) the

lower bound of that in the presently claimed compositions. Applicant respectfully points out that *Haeberlin* discloses dry powder formulations containing the active ingredient formoterol and a carrier such as lactose in a proportion of 400 to 5000 µg of carrier for each µg of formoterol. The upper bound of the concentration of formoterol in *Haeberlin*'s dry powders is actually 1/401, *i.e.*, 0.249%, which is lower than and does not overlap with the claimed lower bound of 0.25%. "Prior art which teaches a value or range that is very close to, but does not overlap or touch, the claimed range does not anticipate the claimed range." See *Manual of Patent Examining Procedure (MPEP)*, 8th Ed., Rev. 5, Aug. 2006, at 2100-71. Thus, *Haeberlin* does not anticipate the claimed invention. Withdrawal of the rejection is requested.

The Examiner has also rejected claims 1-7 under 35 U.S.C. § 102(b) as being anticipated by Keller (WO 00/28979/U.S. Patent 6,645,466, hereinafter "*Keller*"). The Examiner contends that Keller discloses dry powder formulations containing 0.27% w/w active ingredient formoterol, 0.50% w/w magnesium stearate, and 99.23% w/w lactose. Claim 1 has been amended to recite that the claimed dry powder inhalation composition consists of an active ingredient and a pharmaceutically acceptable particulate carrier. Thus, the claim excludes other ingredients such as magnesium stearate. Withdrawal of the rejection is requested.

THE REJECTION UNDER 35 U.S.C. § 103

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over *Haeberlin*. According to the Office Action, this rejection has been made in favor of compact prosecution and in anticipation of Applicant's amendment to recite an amount of active ingredient greater than 0.25% w/w.

The Examiner contends that although *Haeberlin* does not teach dry powder formulations containing more than 0.25% w/w active ingredient, it would have been obvious to a person skilled in the art at the time of the invention to optimize the amounts of formoterol in *Haeberlin*'s compositions according to patient needs. Applicant respectfully disagrees.

As discussed above, *Haeberlin* discloses dry powder formulations containing formoterol and a carrier such as lactose in a proportion of 400 to 5000 µg of carrier for each µg of formoterol, corresponding to 0.02% to 0.249% w/w active ingredient formoterol. *Haeberlin* teaches that such formulations are particularly effective (*see*, *Haeberlin*, page 1, second paragraph). Thus, *Haeberlin* not only would not have motivated a person skilled in the art to produce dry powder formulations containing greater amount of active ingredient, but also teaches away from such dry powder formulations.

The Examiner contends that *Haeberlin's* teaching of dry powder formulations containing from 0.02% to 0.249% w/w formoterol does not constitute a teaching away because it would have been obvious to a person skilled in the art at the time of the invention to optimize the amounts of formoterol in *Haeberlin*'s compositions according to patient needs. Based on *Haeberlin*'s own words, however, namely that the disclosed amounts of formoterol were "particularly effective," it would seem that a person skilled in the art would have believed that amounts of formoterol have already been optimized. A person skilled in the art would not have further "optimized" the amount of formoterol so as to produce a composition in which the amount of formoterol is outside the range disclosed by *Haeberlin*. Moreover, "[a] particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a

recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *MPEP*, 8th Ed., Rev. 5, Aug. 2006, at 2100-71, citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the present case, the claimed dry powder formulations are more accurately metered and provide more uniform and consistent dispersions when dispensed by MDPI devices (see, *e.g.*, the specification at page 3, paragraph 0008). Such dry powder formulations would not have been produced by optimization based on patient needs. Patient needs determine the amounts of the drug delivered to a patient, which may be varied by varying the quantity of the dry powder formulation delivered without varying the proportion of the drug in the formulation.

Therefore, Applicant respectfully submits that the rejection of claims 1-10 under 35 U.S.C. § 103(a) over *Haeberlin* should be withdrawn.

THE DOUBLE-PATENTING REJECTIONS

Claim 7 has been rejected as being identical to claim 6 on the ground of statutory type double patenting rejection. Applicant has canceled claim 7, thereby obviating the rejection.

Claims 1, 4-7 and 9 have been provisionally rejected as being unpatentable over claims 1 and 9-11 of copending Application No. 10/646,361 in view of *Haeberlin*. This is an obviousness-type double patenting rejection. Applicant respectfully requests that a response to this rejection be deferred until such time when it is the only outstanding issue in the application.

Applicant respectfully requests entry of the foregoing amendments and remarks into the file of the above-identified application. Applicant believes that all the pending claims are in condition for allowance. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: June 29, 2007

Respectfully submitted,

By Weining Wang

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